REMARKS/ARGUMENTS

In the specification, the term "amyloid peptide protein" has been changed to " Aβ protein or peptide thereof." Support for this change can be found at page 39, line 20.

Claims 1-87 were pending. By virtue of the present amendment, claims 1-87 have been canceled and rewritten as new claims 88-185 to define more distinctly the special technical feature of the invention.

During a telephone conversation on June 22, 2004 with Examiners Foley and Le, the undersigned and Alan Gordon (Senior Patent Counsel) traversed the restriction requirement and proposed claims similar to those issued to other patentees claiming adjuvant combinations. The Examiners accepted our proposal, and we now present herein a complete set of new claims for review, as well as reiterate our argument against the imposed restriction requirement.

The invention presently claimed herein is directed to an antigenic composition comprising an antigen and an effective adjuvanting amount of the combination of: (1) 3-O-deacylated monophosphoryl lipid A or monophosphoryl lipid A and derivatives and analogs thereof, and (2) a cytokine or lymphokine, or an agonist or antagonist to said cytokine or lymphokine, wherein the combination of adjuvants enhances the immune response in a vertebrate host to said antigen (see new claim 88). The antigen is derived from a pathogenic virus, bacterium, fungus or parasite, or from a cancer cell or tumor cell, or from an allergen, or from an Aβ protein or peptide thereof (see new dependent claims 98-104).

According to 37 CFR 1.475, a national application shall relate to one invention or a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Unity of invention is fulfilled when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Here, that special technical feature is the adjuvant combination that enhances the immune response in the vertebrate to the antigen, regardless of whether the antigen is derived from a pathogenic

virus, bacterium, fungus or parasite, or from a cancer cell or tumor cell, or from an allergen, or from an Aβ protein.

In at least three U.S. national stage applications, each examined by a different examiner, patents were granted to compositions comprising any antigen and a combination of adjuvants. In U.S. Patent No. 6,623,739, claims 1 and 3 read as follows:

1. An immunogenic composition comprising an antigen and/or antigen composition and an adjuvant consisting of a metabolizable oil and alpha tocopherol in the form of an oil in water emulsion.

3. The immunogenic composition according to claim 1 wherein said antigen and/or antigenic composition is prepared from the group consisting of Herpes Simplex Virus type 1, Herpes Simplex Virus type 2, Human cytomegalovirus, HepatitisA, B, C or E, Respiratory Syncytial Virus, Human Papilloma Virus, Influenza Virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium and Toxoplasma, Feline Immunodeficiency Virus, and Human Immunodeficiency Virus.

In U.S. Patent No. 6,544,518, claims 1, 8 and 9 are relevant and read as follows:

1. An adjuvant composition comprising a QS21 and an immunostimulatory oligonucleotide containing an unmethylated CG dinucleotide.

8. An immunogenic composition comprising an adjuvant composition as claimed in claims 1 or 2, further comprising an antigen.

9. An immunogenic composition as claimed in claim 8, wherein said antigen is derived from an organism selected from the group comprising: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex Virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B, C or E, Respiratory Syncytial virus, human papilloma virus, Influenza virus, Hib, Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella,

Streptococcus, Mycoplasma, Mycobacteria, Haemophilus, Plasmodium or Toxoplasma, stanworth decapeptide; or the N terminal 39-43 amino acid fragment (A beta) of the amyloid precursor protein or antigens associated with atheroschlerosis.

In U.S. Patent No. 6,406,705, claims 1 and 8-11 are relevant and read as follows:

1. A composition of a synergistic combination of adjuvants, comprising: an effective amount for inducing a synergistic adjuvant response of a combination of adjuvants, wherein the combination of adjuvants includes at least one oligonucleotide containing at least one unmethylated CpG dinucleotide and at least one non-nucleic acid adjuvant.

8. The composition of claim 1, wherein the composition also includes an antigen that is selected from the group consisting of peptides, polypeptides, cells, cell extracts, polysaccharides, polysaccharide conjugates, lipids, glycolipids, carbohydrates, viruses, viral extracts and antigens encoded within nucleic acids.

9. The composition of claim 8, wherein the antigen is derived from an infectious agent selected from the group consisting of a virus, bacterium, fungus and parasite.

10. The composition of claim 8, wherein the antigen is a tumor antigen.

11. The composition of claim 8, wherein the antigen is an allergen.

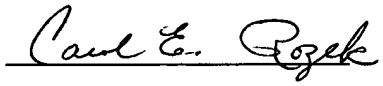
In each of these patents, the technical feature linking the claimed inventions was the adjuvant combination selected to enhance the immune response to a given antigen, whether that antigen be a virus, bacterium, fungus, parasite, tumor antigen, allergen or Aβ protein. For these patents to issue, the unity of invention requirement had to have been fulfilled. Likewise, for the invention as presently claimed herein, the unity of

invention requirement is fulfilled. As such, a restriction requirement of the new claims set forth in this Amendment would be improper.

Furthermore, a search by the Examiner for documents relevant to new claim 88 would necessarily uncover documents relevant to new dependent claims 98-104 (as well as to the other new claims), because all the claims focus on the new technical feature of the specifically recited combination of adjuvants. Thus, no additional burden would be imposed upon the Examiner to perform a search that would encompass the subject matter of all of the claims.

In view of the above amendments and remarks, reconsideration of the application is requested.

Respectfully submitted,



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